

CORE CURRICULUM IN NEPHROLOGY

Management of the Hemodialysis Unit

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Although an in-center hemodialysis facility is primarily perceived as a provider of health care, it is also a business which requires a leader. Analogous to the “Triple Aim” of the healthcare system envisioned by the Centers for Medicare and Medicaid Services (CMS), each hemodialysis facility has its own triple aim: (1) providing each patient with a safe, high quality, pleasing experience of care; (2) complying with CMS’s certification requirements; and (3) assuring that the facility remains financially viable. The common denominator for all three aims is quality of care which is a focus for Medicare survey and certification activities, impacts on patient outcomes and perceptions, and affects payment through the Quality Incentive Program (QIP). The facility medical director is primarily responsible for the Quality Assessment Performance Improvement (QAPI) program within the facility, but must partner with the facility administrator (FA) to assure that resources are directed to address opportunities for improvement. The responsibilities of the medical director have been addressed in detail in a series of articles which appeared in the *Clinical Journal of the American Society of Nephrology* in 2015 and will not be extensively discussed in this article. Both the FA and medical director report to the governing body of the facility and may be members of the governing body. It is ultimately the responsibility of the governing body to adopt and enforce rules and policies to allow for safe and effective care delivery in hemodialysis unit (Table 1). The key responsibilities and qualifications of the FA are summarized in Table 2.

CERTIFICATION AND LICENSURE

The initial ESRD Conditions for Coverage (CfC) were established in 1976 and most recently revised in 2008. To participate in the Medicare or Medicaid programs, facilities must be in

compliance with the Federal rules and standards for dialysis facilities found in the CfC. CMS developed the standards to ensure safe care of the highest quality to dialysis patients. The revised CfC focus on using an interdisciplinary, integrated care system that emphasizes patient assessment, care planning, care delivery, and quality assessment and performance improvement. These new standards also focus on patient satisfaction and involvement in the development of the care plan and treatment. Outcome measures were developed and validated with input from the renal community to ensure they are clinically meaningful and reflect current scientific knowledge. It should be noted that dialysis facilities must comply with the laws and regulations of other local and Federal agencies in addition to the CfC. These are summarized in Table 3.

To provide guidance in the application of these regulations, CMS developed the ESRD Interpretive Guidelines. The guidelines identify regulations with a “V tag” and include the regulation and a point by point interpretation of each condition. There are over 500 V tags so this guidance is particularly helpful with such a large volume and complexity of standards. CMS partnered with others in developing the standards. Some were direct partners whose standards are referred to within the CfC. This includes the Association for the Advancement of Medical Instrumentation (AAMI). This organization developed and updates the standards for Dialysate in Hemodialysis (RD52:2004), Water for Hemodialysis (RD62:2001) and for Reuse of Hemodialyzers (RD47:2002/03). The CfC references and utilizes these AAMI standards in the CfC due to the expertise of AAMI in this important area.

To ensure facilities are in compliance with the standards as well as in the provision of safe, high quality care, CMS requires an initial survey of the facility to achieve certification as an ESRD provider as well as periodic re-surveys thereafter. This survey is delegated to the state Departments of Health by CMS. States may also require separate licensure within the state. The survey process, known as the ESRD Core Survey, uses a risk-based approach based that is data driven. Data are obtained from the Dialysis Facility Report (see Quality Metrics section of this article) as well as other outcomes data sources to determine the priority of facility surveys. The data also focus the survey to problem areas or those with outcomes that are less than expected. Trained surveyors observe for safety hazards related to water and dialysate, reuse, machine operation and maintenance, direct care, interdisciplinary assessment, care planning, and delivery of care. If poor outcomes are identified, it would be expected that the QAPI process in the facility had identified the issues and developed actions to address them. Depending upon what conditions are found to be deficient, the survey can find the facility to be in full compliance or can issue citations at the “Standard,” “Condition,” or “Immediate Jeopardy” level. In issues of “Immediate Jeopardy,” considered life-threatening situations, the state agency has the authority to close a facility until it is considered safe. Helpful information can be found in the ESRD Core Survey Field Manual, the surveyor “Laminates” and the Measures Assessment Tool (MAT) on the CMS website.

Additional Readings

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PERSONNEL

The FA is responsible for ensuring that adequate numbers of qualified staff are in place to care for patients. This includes the recruitment and appointment of medical staff physicians and non-physician practitioners such as advanced practice nurses and physician assistants. The CfC

specify that an adequate number of qualified and trained staff must be present when patients are undergoing dialysis to ensure that the appropriate dialysis care and patient needs are met. While a specific staff/patient ratio is not defined, the FA must meet any applicable state regulations. Consideration must be given to the acuity and care needs of the patients who will be served and the expertise of the staff in those areas. Adequate staffing ratios must be present to be able to see every patient during treatment and provide routine care, assessment, and monitoring as well as respond to changes in patient conditions or emergency situations. The roles and qualifications of key patient care personnel in the dialysis facility are summarized in Table 4.

The interdisciplinary team (IDT) is composed of the patient's nephrologist, an RN familiar with the patient, the dietitian and social worker involved in the patient's care, and other personnel as appropriate. The RN performs an initial and ongoing comprehensive assessment of the patient and seeks the patient's and family's input into care goals. The patient is expected to be a member of his/her IDT and a participant in the discussion regarding his/her plan of care. On a regular basis the RN reviews the patient's lab work, medications, and other concerns and brings them to the attention to the IDT to re-evaluate and revise the plan of care as needed. Patients are taught about their disease and the various aspects of treatment. Patients are informed about all renal replacement options including transplantation and are supported in their decisions to investigate these options.

The FA must ensure that all staff have the appropriate licensure, certifications, and have successfully completed a training program and orientation to prepare them for their role in the

care of dialysis patients. There must be a process to provide and document ongoing education and competency testing to ensure safe, effective practice including emergency situation response. Staff not found to be competent must be retrained. Employees must have periodic health screening and must also meet the Federal and any state guidelines including tuberculosis testing and hepatitis B.

The FA must also ensure that there are adequate numbers of staff and staff mix as well as professionals needed to support the QAPI process. The FA has the responsibility along with the medical director to ensure the quality of services being provided in the facility. There must be communication between the FA and the governing body regarding the QAPI program. Areas of need require planning and action with follow-up to determine the effectiveness of interventions. The need for staff requires a thorough assessment of quality data by the governing body and QAPI committee to determine areas requiring improvement. Once the determination has been made, the FA must develop a plan to meet the needs in a fiscally responsible manner. If it is determined that issues are more related to a need for practice or process changes or education, the FA must ensure that those plans are developed, operationalized and evaluated to determine effectiveness. If individual performance issues are found, staff must be held accountable and a plan of re-education and competency testing or corrective disciplinary action taken. This is reported to the governing body as well. The differences between the IDT and QAPI committee are summarized in Table 5.

Education needs are considerable in dialysis facilities and include orientation and initial competency testing of all staff as well as ongoing education and re-testing. The development

and provision of a patient care technician (PCT) training program must include the elements of patient care, understanding ESRD and its related conditions, machine technology, water treatment, infection control, patient education concepts, and understanding of quality components and the QAPI process. Effective staff recruitment and hiring as well as ongoing staff retention is an important area of focus for the FA. Reviews of salaries and benefit options for competitiveness as well as financial impact must be done on a regular basis. This also requires an understanding of labor laws and practices, workers compensation, Family Medical Leave Act regulations, Americans with Disabilities Act requirements, affirmative action, and other human resource related topics.

Additional Readings

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FINANCES

Budget and Costs

Fiscal responsibility is a key role of the facility administrator. Capital and operating budgets must be developed annually and monitored for expense variances to budget. An operating budget is a detailed projection of all estimated income and expenses based on forecasted revenue for the upcoming year. It generally consists of several sub-budgets, the most important one being the expected revenue budget which is prepared first. Preparing an operating budget requires a balancing act of analyzing the existing data for revenue and expenses, then forecasting the numbers for the year ahead based upon knowledge of volume, revenue or expense changes. Since capital expenses are long term costs, they are excluded from the operating budget. Major items to be considered in an operating budget are listed in Table 6. Revenue begins with correctly capturing complete and accurate data at the time the patient is dialyzed. In addition to careful case management and process reviews, it involves complete charge capture with accurate coding. Claims must then be prepared and submitted with follow-up with payers as needed. The handling of rejections and appeals is important as are opportunities to accelerate collection of accounts receivable and prevention of bad debt.

It is important for the FA to calculate a break-even point to determine how much to charge or how much patient care volume must be delivered to cover costs. In other words, the revenue collected from providing dialysis services must equal or exceed the costs to provide them. Since payment for healthcare is more fixed than in many industries, this calculation often distills down to a patient volume analysis. All costs must be considered in the budgeting process. Fixed costs must be determined and then divided by expected volume to determine fixed costs per treatment; costs such as labor and supplies can be calculated and analyzed on a cost per treatment; total cost includes both fixed and variable costs. Total revenue would be the expected revenue per treatment multiplied by the expected volume. Even in a not for profit business, there must be a favorable margin that is reinvested in the facility to support growth and unanticipated costs.

Reimbursement

Medicare

Public law 92-603, the Social Security Act of 1972, provides Medicare eligibility for patients with ESRD. If the patient already receives Medicare benefits due to being disabled or age ≥ 65 , Medicare payment for dialysis begins immediately. If the patient does not already receive Medicare benefits, full Medicare benefits including payment for dialysis begins the first day of the third calendar month after the Medical Evidence Report (form 2728) certifying that the patient has ESRD is signed by the nephrologist. Only patients who have paid into the Social Security system for a total of 20 quarters, or are a dependent of someone who has, can qualify

for Medicare benefits. Medicare part B pays 80% of the cost of dialysis (“primary”); the patient needs co-insurance to pay the other 20% (“secondary”). If the patient has employer-paid group health insurance at the time he/she develops ESRD, the commercial insurance is primary for 30 months if the patient is already Medicare eligible, or 33 months (the 3 month waiting period with no Medicare plus 30 months) if the patient is already Medicare eligible. Medicare is the secondary (20%) payer (MSP) during the 30 monthly “coordination of benefits” period. The 3 month Medicare waiting period is waived if a patient initiates home dialysis training or undergoes renal transplantation during the waiting period. In the case of home dialysis training, Medicare becomes effective the first day of the month that home training began. In the case of kidney transplant, Medicare becomes effective the first day of the month of the transplant or up to two months before if transplant evaluation was initiated during that period. The 30 month MSP period still applies for home dialysis patients.

The concept of bundling payment for dialysis patients was initiated in 1981; however it has been revised substantially with the Medicare Improvement for Patients and Providers Act (MIPPA) in 2009 which established a bundled reimbursement system for dialysis to include the previous “composite rate” items and services, injectable drugs and oral equivalents, and additional previously separately billable lab tests beginning in 2011. The primary goal of the bundled payment system was disincentivize the overuse of the drugs that were previously separately reimbursable. The original MIPPA legislation provided for the inclusion of oral ESRD drugs with no intravenous equivalent (such as phosphate binders and calcimimetics) into the bundle in 2014. Subsequent legislation has postponed the inclusion of these drugs into the bundle to 2024.

Medicaid

Medicaid is the healthcare safety net for low-income patients in the US. Patients who qualify for Medicare as primary payer for dialysis (80% payment) may also qualify for Medicaid if they meet low-income requirements that vary by state. Patients who have both Medicare and Medicaid coverage are termed “dual-eligible”. Dialysis patients who do not qualify for Medicare because they have not contributed to the Social Security system for 20 quarters or are a dependent of someone who has may qualify to receive Medicaid benefits as their sole source of dialysis payment. For patients who are dual-eligible (Medicare 80%, Medicaid 20% payment), reimbursement for the 20% due from Medicaid varies by state; some states do not pay the full amount and some states pay nothing at all. For patients who are Medicaid-only, most states pay the dialysis facility significantly less than the Medicare-allowable amount which may be far less than the cost of the treatment. Since Medicare covers only 80% of the cost of dialysis, patients who do not qualify for Medicaid must seek co-insurance or “Medi-Gap” coverage for the remaining 20%. Some states do not allow Medi-Gap coverage to be sold to Medicare patients under 65 years old, so those patients are left with no co-insurance.

Commercial Insurance

Patients with commercial insurance as their primary payer are generally those who are in the 30 month (if already eligible for Medicare due to age ≥ 65) or 33 month (if not already eligible for Medicare due to age < 65) “coordination of benefits” period with an employer-paid health plan. Commercial insurance typically pays for dialysis treatments at several times the Medicare

rate which is individually negotiated with the dialysis provider or its parent company. The dialysis treatment margin provided by commercial payers compensates for the negative margins on Medicaid patients. In some dialysis organizations, a favorable payer-mix in one facility compensates for an unfavorable payer-mix in another facility that is operating at a loss and, if independent, could not survive economically.

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PHYSICAL ENVIRONMENT

In addition to clinical care activities and financial oversight, consideration and attention must be paid to issues related to the physical environment of the dialysis facility. Physical environment requirements of the CfC address building safety, equipment maintenance, the patient care environment, emergency preparedness, and fire safety. This includes the assurance of proper maintenance and repair of such items as the dialysis equipment, operating systems, water treatment systems, and the physical building and grounds.

In a healthcare space such as a dialysis facility, patients usually occupy 70% of the space with other services using the 30%. Full visibility is a part of the standards and requires all patients to be fully visible to staff at all times. The space should be both safe and efficient, but also pleasant and conducive to patient needs during treatment as well as during other activities in the facility. The dialysis facility must ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) is maintained and operated in accordance with the manufacturer's recommendations.

Additional items are covered in the physical environment section of the CfC apply to patient comfort and privacy. Consideration must be given, for example, to the environmental temperature so that it is comfortable for both patients and staff. Patients who feel cold must be allowed to use blankets, whether provided by the patient or the facility. The patient must be able to have privacy when examined or treated and body exposure is required. Despite the need for privacy, patients should be in direct view of staff at all times during treatment. This allows staff to monitor patients for untoward reactions to dialysis or accidental needle removal

or disconnection. Patients must have their faces and accesses uncovered at all times to allow staff to monitor their safety. There should be a mechanism for both patients and staff to give regular feedback and share concerns about safety or quality issues.

Emergency Preparedness

Dialysis facilities must have plans for emergency preparedness that include fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. Facilities may prepare for other types of emergencies including bioterrorism or active shooters which are identified as risks after the performance of a facility risk assessment. In addition to having a plan for emergency management, the dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff and must be evaluated at least annually. This includes quarterly fire drills that involve both staff and patients. Patients also must be educated and prepared for emergency situations. The frequency of this training must be sufficient so that staff and patients are able to implement emergency plans. State or local fire codes must be met. All other Life Safety Code (LSC) provisions in New and Existing Ambulatory Health Care Occupancies apply to dialysis facilities, including provisions regarding automatic notification-equipped fire detection and alarm systems. Dialysis facilities must have a plan and educate staff and patients where to go during an emergency. Dialysis facilities should provide an alternate phone number for patients under circumstances when the dialysis facility is unable to receive phone calls due to an emergency. The FA should establish contact with its local disaster management agency at least

once a year to ensure that they are aware of the dialysis facility's needs in the event of an emergency.

Nurses at the facility should be trained and prepared to handle clinical emergencies that are likely to occur in dialysis. The facility should have equipment available for treating medical emergencies such as suction machines and defibrillators. Nurses and patient care technicians must be certified in CPR. The specific emergency drugs that are to be available should be determined by the medical director and described in the facility's policies and procedures.

Water Quality

Water quality is the responsibility of the medical director and a detailed discussion is beyond the scope of this article. Without appropriate monitoring and maintenance of water quality the lives of patients are placed at significant risk. There have been numerous occasions with catastrophic events as a result of poor water quality. Water quality is mentioned frequently in the CfC and is a frequent trigger for citation by state surveyors. The water technician should review the AAMI guidelines annually and incorporate the most recent recommendations into practice. State surveyors will directly observe chlorine/chloramine testing in a dialysis unit, interview staff to assess their fund of knowledge and competency regarding water quality, and review documentation of testing and maintenance of the water system. The recommended frequency of checking for chlorine/chloramines, the appropriate calibration of a conductivity meter, and the proper preparation of the bicarbonate mix are all processes that involve multiple individuals and the procedures must be standardized to minimize error.

Water quality measurements include chemical, electrolyte and microbial levels. Some compounds that deserve special attention include aluminum, chloramine, fluoride and nitrate. Aluminum at high levels is detrimental to bone, hematologic and neurologic axes. Chloramines and nitrates can induce methemoglobinemia. CMS requires that the total viable microbial count must be lower than 200 CFU/mL and endotoxin concentration less than 2 EU/ml; however, the action level is 50 CFU/ml and 1 EU ml respectively for product water, i.e. water used to prepare dialysate. At the action level the typical plan is to repeat cultures and sometimes to disinfect the system and again repeat cultures. Documentation of the testing, results, and the action plan for water quality is critical to the successful management of a hemodialysis unit. Whether to continue dialysis or stop dialysis and the specifics of the action plan is based on the final determination by the medical director; however the medical director relies on the QAPI team and in particular the lead water technician to present the abnormal data and potential action plans. Water quality is an important component in the monthly QAPI meetings and the status of the facility's water and any deviations in protocols or quality metrics are subject for review. It can be helpful to bring any available logs to present the group at the monthly QAPI meetings to make everyone aware of the shared responsibility of water quality. Water quality assurance is a team effort and vital for the safe care of dialysis patients.

Infection Control

Infection control is the responsibility of the medical director and a detailed discussion is beyond the scope of this article. Infection control issues are often cited by state surveyors. All facility staff should be held accountable for infection control. Handwashing is essential for infection

control in a hemodialysis unit. Gloves should be worn prior to patient contact or equipment manipulation. Hands should be washed before and after use of gloves and gloves should be changed whenever soiled or when moving from one patient chair to another as well as anytime access manipulation or intravenous medication administration occurs. The facility must be designed with enough sinks to facilitate handwashing and separate utility sinks for cleaning equipment.

Staff should wear personal protective equipment which includes designated garments with sleeves, appropriate to the anticipated potential exposure and the most robust protection should be used during high risk components of the dialysis procedure such as treatment initiation and termination. Any items that are in the patient's dialysis station could become contaminated and should be handled with caution and cleaned after the treatment, for example, a patient's blanket. Staff should be vigilant along with patients not to cross contaminate clean and dirty equipment. For example, unused medications would be "clean" and used needles would be considered "dirty." The patient treatment area should have designated "clean" and "dirty" partitions. Disinfection of the dialysis treatment equipment should be done according to manufacturer's guidelines. At the end of every patient treatment the dialysis station needs to be thoroughly cleaned.

Hepatitis and Isolation

Cleaning equipment and following proper isolation protocols is essential to infection control. Hepatitis serologic evaluation is important to prevent the transmission of hepatitis B among ESRD patients. All new patients should have HBsAg, total anti-HBc, and anti-HBs results known prior to admission for treatment. If the results of this testing are not known at admission

because of an emergency situation, the patient should be tested as soon as possible. Any patient whose anti-HBs level is less than 10 mIU/mL should have HBsAg tested monthly. Those patients who have received and responded to the hepatitis B vaccine should have anti-HBs titer measured annually to determine whether a booster dose of the vaccine is needed. All patients and staff whose anti-HBs level is less than 10 mIU/mL should be offered the vaccine. HBsAg-positive seroconversions must be reported to the health department as required by local regulation. Patients with a positive HBsAg must be isolated and there should be follow up testing to determine when the patient may be taken out of isolation. State surveyors may look for documentation for seroconversions including actions taken in response as well as analysis to evaluate for potential transmission of the virus within the facility. HBsAg-positive patients should dialyze in separate isolation rooms, although in facilities built prior to the 2008 update in regulations any separate isolation area would suffice. There must be separate equipment for HBsAg-positive patients and staff members should not be caring for both HBsAg-positive and HBsAg-negative patients simultaneously.

In January 2016, the Centers for Disease Control and Prevention (CDC) issued an advisory to dialysis facilities because of an increased number of reports of newly acquired hepatitis C (HCV) infection among hemodialysis patients. CDC urged dialysis providers to assess current infection control practices to insure adherence to infection control standards; address any gaps identified by the assessments; screen patients for HCV according to CDC guidelines to detect infections, determine treatment potential and halt secondary transmission; and promptly report all acute HCV infections to health authorities. CDC recommends that all hemodialysis patients be screened for HCV antibody (anti-HCV) upon admission to the dialysis facility and

every 6 months thereafter. For patients with positive anti-HCV, nucleic acid testing for HCV RNA is recommended to confirm infection. Any HCV seroconversion of a hemodialysis patient should trigger QAPI activities to determine the source of the transmission.

Staff must be oriented to infection control policies and procedures at the start of employment as well as annually at a minimum. Infection control is another integral part of the facility's QAPI meetings and discussion of infections and action plans should be recorded and available for review.

Immunizations

Hepatitis B vaccination is recommended for susceptible patients undergoing chronic dialysis. All patients should undergo annual influenza vaccinations unless there is a specific contraindication. The newer pneumonia vaccination guidelines recommend that for patients who have never received the pneumococcal vaccine, adults should receive a dose of first PCV-13 then a dose of PPSV23 a minimum of 8 weeks following PCV13. Patients who previously received PPSV23 should receive a dose of PCV13 at least one year after the most recent PPSV23.

Violence in the Dialysis Facility

The dialysis facility has many diverse people in one space at a given time. Conflicts are inevitable but need to be addressed in a systematic way to help diffuse tension and promote safety for both patients and staff. CMS and the ESRD Networks carefully review all involuntary patient discharges. Facilities must follow protocols carefully for any involuntary discharges (IVD) or involuntary transfers (IVT) or the facility may be subject to sanctions from CMS. There

must be documentation of multiple attempts to resolve the issues of conflict prior to patient discharge or transfer, including the following required steps: (1) notification of the ESRD Network; (2) comprehensive reassessment and revision to plan of care to address the problem; (3) documentation of the ongoing issues and effect on others individuals and the facility; (4) documentation of steps to resolve conflict; (5) documentation of patient's response to interventions; (6) written orders for IVD or IVT must be signed by attending and medical director; (7) the patient must be given a minimum of 30 days' notice of impending IVD or IVT. If a patient is an imminent threat to the safety to patients or staff, the patient can be immediately transferred or discharged and law-enforcement authorities should be promptly notified. The social worker is a critical liaison in helping address conflict.

Any member of the facility staff could also be participating in disruptive behavior. Ultimately the staff managers should give feedback and develop a plan to improve behavior, but if these interventions are not productive disciplinary action may need to be taken. The medical director should be notified in a timely manner so they he/she may contribute to the improvement plan.

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QUALITY METRICS

The QAPI team is responsible for ongoing quality assessment and performance improvement in the dialysis facility. The QAPI team includes the medical director, facility administrator, social worker, dietitian, and any other stakeholders in the quality improvement effort, such as a water treatment system technician, infection control expert, and/or nurse with a particular area of responsibility (e.g. anemia or vascular access management). Some quality metrics are publicly reported and affect payment, so these can have a significant impact on patient census and the financial health of the facility.

The Measures Assessment Tool

The CfC for dialysis facilities were last revised in 2008 and because the CfC cannot adapt to changes in the standards of care for anemia, mineral metabolism and vascular access, for

example, CMS has purposely excluded such quality metrics from the CfC and included them in the ESRD Interpretive Guidelines used by state surveyors as a guide to the survey process. Metrics included in the interpretive guidelines can be changed at will by CMS in response to changes in medical practice since they do not require written legislation or regulation. The set of quality metrics used by state surveyors is known as the Measures Assessment Tool (MAT) and since these measures do not involve public reporting or payment, their use does not require a strong evidence basis or vetting by a consensus panel from the ESRD community. It is intended that state surveyors use these measures not as a “pass/fail” grading system, but rather to determine whether a facility has undertaken the appropriate QAPI process if the results of the measure demonstrate opportunities for improvement. Key patient-level indicators in the MAT as of the time of this writing include hemoglobin level, indicators of iron status, serum calcium, serum phosphorus, PTH level, dialysis adequacy, dialysis duration, serum albumin level, weight loss, overall infection rate, patient immunizations, arteriovenous fistula prevalence, prevalence of central venous catheters >90 days, vascular access thrombosis rates, vascular access infection rates, vascular access patency, patient quality of life, patient experience of care, patient grievances, patient survival and hospitalizations.

The Dialysis Facility Report

The Dialysis Facility Report (DFR) is an annual report provided as a resource to each dialysis facility for characterizing selected aspects of clinical experience at the facility compared to other caregivers in the state, ESRD Network, and the US. The DFR is based on data from Medicare claims and CROWNWeb and provides demographics of patients in the facility;

standardized ratios (observed/expected counts based on case-mix) for mortality, hospitalization, and transplantation; transplant waitlist and influenza vaccination rates; and clinical data including hemoglobin level, adequacy of dialysis, and vascular access. The DFR can be useful for internal quality improvement activities at a facility. The report is also distributed to the respective state Department of Health and may trigger a facility survey if there are significant perceived deficiencies. The DFR is distributed to the ESRD Network and may trigger targeted quality improvement activities directed by the Network.

Dialysis Facility Compare and 5-Star Rating

Dialysis Facility Compare is a publicly available website

(www.medicare.gov/dialysisfacilitycompare) that allows any individual to view quality metrics from dialysis facilities and to compare selected facilities side-by-side. The data derived primarily from CROWNWeb and Medicare claims are usually revised in the third or fourth calendar quarter to include the previous calendar year. The DFC metrics at the time of this writing include (1) standardized transfusion ratio (STrR, based on Medicare claims and case-mix adjusted), (2-4) dialysis adequacy, (5) fistula prevalence, (6) prevalence of dialysis catheters >90 days, (7) hypercalcemia (percentage of patients with 3-month average serum calcium >10.2 g/dL), (8) standardized mortality ratio (SMR), (9) standardized hospitalization ratio, and standardized hospital readmission ratio. These nine metrics (including 3 for dialysis adequacy: adult hemodialysis, pediatric hemodialysis, and adult peritoneal dialysis; excluding standardized hospital readmission ratio) are grouped into three domains: (1) standardized outcomes (STrR, SMR, and SHR); (2) vascular outcomes (fistula prevalence and catheter prevalence); and (3)

other outcomes (all dialysis adequacy and hypercalcemia). Each domain is given a score from 0 to 100 by averaging the normalized scores within that domain. A final score between 0 and 100 is obtained by averaging the 3 domain scores. A dialysis facility is awarded its star rating based its total score's relative position compared to all other facilities rather than the total score itself. The facilities with top 10% scores receive 5 stars, facilities with the next 20% highest scores receive 4 stars, facilities in the middle 40% of scores receive 3 stars, facilities with the next 20% lower scores receive 2 stars, and facilities with the bottom 10% of scores receive 1 star.

The Quality Incentive Program

The Medicare Improvement for Patients and Providers Act (MIPPA) legislation in 2009 which established the bundled payment system for dialysis also mandated the establishment of a quality incentive program (QIP). The rationale is that since bundling shifts what were previously separately billable items from being profit centers to being cost centers for the provider, the patient must be protected from underutilization of resources with performance measures that affect payment and public reporting. MIPPA prescribes that the QIP for dialysis is a 2% withhold from the bundled payment, some or all of which can be earned back by the provider by achieving prespecified performance benchmarks. Since the QIP allows the provider to earn some or all of its bundled payment back but does not provide any additional payment to high achievers, it is a penalty system and not a reward system. The QIP penalty, if there is one, is in increments of 0.5%, and affects all of a dialysis facility's Medicare payments for an entire calendar year, known as the payment year (PY). The QIP penalty is determined for a

given PY based on the facility's performance 2 years prior. So, for example, a facility's QIP penalty for PY 2019 will be based on its performance in 2017. The performance data are collected in real time during the performance year from Medicare claims and from additional information submitted electronically to the CROWNWeb reporting system which has been utilized since 2013. Mandatory QIP measures in MIPPA are anemia management, dialysis adequacy, and patient satisfaction (to the extent feasible). Discretionary QIP measures in MIPPA are iron management, mineral metabolism, and vascular access. The QIP began in PY 2012, based on performance data from 2010. At that time, CMS was able to collect performance data only on anemia management and dialysis adequacy from claims, so those were the only two domains in the QIP for PY 2012 and 2013. By 2012 Medicare claims forms were modified to include vascular access, so the QIP for PY 2014 included anemia management, dialysis adequacy, and vascular access. The inclusion of data from CROWNWeb in performance year 2013 has allowed Medicare to expand the QIP to embrace additional domains as directed by MIPPA, starting in PY 2015. The QIP for PY 2015 and beyond includes clinical measures and reporting measures. The clinical measures are scored according to national benchmarks established during the year prior to the performance year. So for the clinical measures in PY 2019, the performance year was 2017 and the benchmarks are established based on national data from 2016. For each of the clinical measures there is an achievement score and an improvement score. The facility is able to claim the better of these two scores. The achievement score is calculated on a 10-point scale between the national achievement threshold (15th percentile from the year prior to the performance year) and the national benchmark (90th percentile). So, for example, if a facility has an AVF prevalence rate of 54%,

the achievement threshold is 46%, and the benchmark is 74%, the facility would receive 3 points for that measure since 54% is 3/10 of the distance from 46% to 74%. The improvement score is calculated on a 9-point scale between the facility's prior year performance on the measure and the national benchmark. So, for example, if a facility has an AVF prevalence rate of 54%, a prior year AVF prevalence rate of 26%, and the benchmark is 74%, the facility would receive 5 points for that measure since 54% is 5/9 of the distance from 26% to 74%. Since the improvement score is higher than the achievement score in this example, the facility can claim the 5 point improvement score for that measure.

In addition to the clinical measures for PY 2015 and beyond there are also reporting measures which are scored based on whether or not a facility provided the required data to Medicare but not on the quality of care represented by those data. For PY 2019 the clinical measures will include adequacy of dialysis (a composite of adult hemodialysis (HD), adult peritoneal dialysis (PD), pediatric HD and pediatric PD), vascular access (prevalence of arteriovenous fistulas and catheters >90 days), hypercalcemia, NHSN bloodstream infections (outcomes not just reporting), standardized hospital readmission ratio, standardized transfusion ratio, and patient experience of care (ICH-CAHPS outcomes, not just reporting that the instrument was administered). Reporting measures for PY 2019 will include anemia management (hemoglobin level and erythropoietic stimulating hormone dose), mineral management (serum calcium, phosphorus, and PTH levels), pain assessment and follow-up, depression screening and follow-up, personnel influenza vaccination, and rate of fluid removal on hemodialysis. Clinical measures will comprise 90% of the weighted score and reporting measures 10%.

ESRD Networks

The ESRD Networks work with consumers and providers of care for ESRD patients to refine care delivery systems and improve the quality of care for this vulnerable population. The Networks have access to facility-specific data from DFR and CROWNWeb which allows them to target quality activities to facilities with the greatest opportunity for improvement. The Networks provide educational resources, support services and other tools to assist both patients and providers. The Network also provides assistance to evaluate and resolve patient grievances and ensure patients' rights are maintained while reducing involuntary discharges. ESRD Network activities are defined by their scope of work, which is revised annually based on what CMS perceives as the greatest areas of need for quality improvement in the ESRD program. The quality metrics for the MAT, DFC, 5-Star Rating, QIP for payment year 2019 and domains of Network quality improvement activities for the 2016 scope of work are summarized on Table 7.

The ESRD Networks offer a 5-Diamond Safety Program to assist dialysis facilities in improving staff and patient awareness regarding specific patient safety issues and promoting a culture of safety. The program consists of educational modules, and the completion of each module earns a "Diamond" for the facility. The topics of the modules are listed in Table 8.

Additional Readings

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Table 1: Key Requirements of the Governing Body

- Adopt and enforce rules relative to
 - Facility governance
 - Healthcare and safety of patients
 - Protection of patients' personal and property rights
 - General operation of the facility
- Facilities that are part of a dialysis organization with multiple facilities must have a local governing body within each facility
- The governing body may consist of one person or a group of persons
- It must be clear in governing body records
 - The composition of governing body
 - Who has legal authority for the governance and operation of the facility

Table 2: Facility Administrator

- Responsibilities
 - Fiscal management
 - Staff training and coverage
 - Medical staff appointments and coverage
 - Quality assessment and process improvement program
 - Internal grievance process for patients
 - Emergency coverage and backup
 - Electronic data submission
 - Relationship with the ESRD Network
- Qualifications
 - Must possess sufficient educational and practical experience to fulfill the expectations of the role
 - If also acting as nurse manager
 - Registered nurse
 - At least 12 months clinical nursing experience
 - An additional 6 months experience providing nursing care to dialysis patients
 - Must be a full time employee of the facility
 - May not cover more than one facility

Table 3: Selected Laws and Regulations Affecting Dialysis Facilities

State and Local

- Local life safety codes
- Local building codes
- State dialysis facility licensure laws (if applicable)
- State board regulations regarding medical, nursing and pharmacy practice

Federal

- Occupational Safety and Health Administration
- Office of the Inspector General
- Clinical Laboratory Improvement Act
- Centers for Disease Control and Prevention
- Americans with Disabilities Act
- Family Leave Medical Act

National Organizations

- Association for the Advancement of Medical Instrumentation

Table 4: Hemodialysis Facility Personnel

POSITION	MAJOR RESPONSIBILITIES/QUALIFICATIONS
Medical director	<ul style="list-style-type: none"> • Delivery of patient care and patient outcomes • Facility quality assessment and performance improvement program • Assuring staff are adequately trained • Approval of training and educational materials • Development, review and approval of patient care policies and procedures • Ensure adherence to policies and procedures by staff (including all attending physicians and mid-level providers)
Charge nurse	<ul style="list-style-type: none"> • RN or LPN who meets practice requirements in the state • Must have 12 months nursing experience including 3 months providing nursing care to patients undergoing dialysis • An RN must be present at all times when there are patients in the facility • A charge nurse must be designated and present for each patient shift
Nurse	<ul style="list-style-type: none"> • Delegates care to PCT (if applicable) when patients arrive for treatment • Assesses patients before, during and after dialysis • Evaluates patient's response to dialysis • Develops plan and carries out action to meet patient's needs • Participates with IDT to perform initial and ongoing comprehensive assessment and POC for patients • Seeks patient's and family's input into care goals and keeps them informed of recommendations of IDT • Reviews lab work, medications and other concerns and informs IDT to re-evaluated and revise POC. • Assist in education of patients about disease and treatment including all RRT options (home dialysis and transplantation)
Patient care technician	<ul style="list-style-type: none"> • Defined by CMS as any unlicensed staff member who has responsibility for direct patient care • Responsibilities subject to the limitations of state law but may include: preparing dialysis apparatus, performing equipment safety checks, initiating dialysis including cannulation, IV administration of heparin and normal saline, subcutaneous or topical administration of local anesthetics, monitoring patients during dialysis, documenting tasks and observations • Must have high school diploma and at least 3 months experience under direct supervision of an RN

	<ul style="list-style-type: none"> • Must complete a training program including specified topics approved by the medical director and governing body • Must be certified by a CMS-approved or national PCT certification program within 18 months of hire
Water treatment system technician	<ul style="list-style-type: none"> • Must complete a training program including water testing, risks and hazards of improperly prepared dialysate, and bacterial issues • Training must be done and competency ensured in the use of equipment by the manufacturer • Training specific to tasks performed such as mixing dialysate, disinfection of equipment, equipment maintenance and repairs • Periodic audits of compliance with testing of technician's knowledge and skills • Training program approved by the medical director and governing body
Dietitian	<ul style="list-style-type: none"> • At least 1 year of professional work experience as a renal dietitian • Must be able to perform complex nutritional assessments and evaluate laboratory results • Assist IDT in managing anemia, renal bone disease, performing kinetic modeling • Monitoring patients' adherence and response to diet • Recommend interventions to improve nutritional issues • Participate in POC and QAPI program • May be shared between facilities
Social worker	<ul style="list-style-type: none"> • Master's degree in social work with specialization in clinical practice • Must be skilled in assessing patient's psychosocial situation and how it will impact or influence treatment outcomes • Interventions designed with the IDT , patient and family to maximize the effectiveness of treatment • Use of validated tools such as the SF-36 and KDQOL to improve care and monitor the outcomes of directed interventions • Counseling services as needed • Assist patients in adapting to chronic disease • Participate in POC and QAPI program • May be shared between facilities

RN=registered nurse; LPN=licensed practical nurse; PCT=patient care technician; IDT=interdisciplinary team; POC=plan of care; RRT=renal replacement therapy; CMS=Centers for Medicare and Medicaid Services; POC=plan of care; QAPI=quality assessment and performance improvement; SF-36=Medical Outcomes Study 36-item short form survey; KDQOL=Kidney Disease Quality of Life

Table 5: Comparison between Interdisciplinary Team and QAPI Committee

	Interdisciplinary Team	QAPI Committee
Level of focus	Individual patient	Facility system
Goal	Develop individualized plan of care	Improve system processes and outcomes
Chair	Patient's nephrologist	Facility medical director
Members	Nurse, dietitian social worker; patient participates during or after meeting by discussing and signing-off on his/her plan of care	Facility administrator, dietitian, social worker, others stakeholders of processes as appropriate
Frequency of meetings	Within 30 days of patient's arrival in facility, 3 months after patient's arrival, annually after patient's arrival; monthly if patient is unstable	Monthly; more frequently as appropriate for rapid-cycle improvement

QAPI= quality assessment and performance improvement

Table 6: Major Items in an Operating Budget

EMPLOYMENT COSTS

- Salaries
- Contract labor
- Orientation and education
- Benefits

NON-EMPLOYMENT DIRECT COSTS

- Medical supplies and pharmaceuticals
- Equipment lease and rentals
- Repair and maintenance

NON-EMPLOYMENT INDIRECT COSTS

- Office supplies
- Utilities
- Rent
- Association fees
- Administrative expenses
- Contracted services (laundry, housekeeping, landscaping security)

Table 7: Quality Metrics for Dialysis Facilities

Measure	MAT	DFR	DFC and 5-Star	QIP (PY 2019)	Networks (2016 SOW)
Hemoglobin	x	x		Reporting	
ESA dose				Reporting	
Iron status	x				
Transfusions			x	Clinical	
Serum calcium	x		x	Clinical	x
Serum phosphorus	x			Reporting	
PTH level	x			Reporting	
Dialysis adequacy	x	x	x	Clinical	
Dialysis duration	x				
Serum albumin	x				
Body weight loss	x				
Overall infections	x				x
Immunization of patients	x	x			x
AVF prevalence	x	x	x	Clinical	x
CVC prevalence	x	x	x	Clinical	x
VA infections	x				x
VA thrombosis	x				
VA patency	x				
Patient QOL	x				
Experience of care	x			Clinical	x
Patient grievances	x				x
Survival (SMR)	x	x	x		
Hospitalizations (SHR)	x	x	x		
Readmissions			x	Clinical	
Care transitions					x
Transplantation referral	x	x			x
Home dialysis referral					x
Immunization of staff				Reporting	
Rate of fluid removal				Reporting	

MAT=Medical Assessment Tool; DFR=Dialysis Facility Reports; DFC=Dialysis Facility Compare; QIP=Quality Incentive Program; PY=payment year; SOW=scope of work; ESA=erythropoietic stimulating agent; PTH=parathyroid hormone; AVF=arteriovenous fistula; CVC=central venous catheter; VA=vascular access; QOL=quality of life; SMR=standardized mortality ratio; SHR=standardized hospitalization ratio

Table 8: Topic Areas in the 5-Diamond Safety Program

Patient safety principles	Medication reconciliation
Communication	Missed treatments
Constant site cannulation	Patient-provider conflict
Emergency Preparedness	Patient self-managed care
Hand hygiene	Sharps safety
Health literacy	Slips, trips and falls
Influenza vaccination	Stenosis/vascular access monitoring
Transplantation	